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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,238	12/05/2001	Lawrence A. Shimp	525400-208	8543

7590

10/09/2003

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/09/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,238

Applicant(s)

SHIMP ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-138 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 18-20, 22, 23, 25-29, 33, 60-63, 72, 73, 80, 86, 87, 114-116 and 127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 9, 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11,15-17,21,24,30-32,34-59,64-71,74-79,81-85,88-113,117-126 and 128-138.

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The Official Draftsperson has approved the Formal Drawings filed on October 9, 2002.

Applicant's election with traverse of Species 7 and Group I in Paper No. 8 is acknowledged. The traversal is on the grounds that any search of the implant claims requires a full search in reference to the pins. This is not found persuasive because there are certainly classes and subclasses in which one would reasonably expect to find pins (606/72-73 being but one example) but not the implant as claimed. The requirement is still deemed proper and is therefore made FINAL.

In the Information Disclosure Statement of December 5, 2001, the Swedish patent document was **not** considered because a concise explanation of the relevance (37 C.F.R. § 1.98(a)(3)) was not presented. The two Albee articles (listed at the very bottom of page 1) were not considered because copies were not found among the papers (37 C.F.R. § 1.98(a)(2)).

The disclosure is objected to because the omitted data should be added on page 1 and elsewhere in the specification. In claim 127, line 7, "demineralized" is misspelled. Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 114-116 are rejected under 35 U.S.C. 101 because of the positive recitation of the "vertebral load" (claim 114, line 3) and thus the vertebrae of the patient (MPEP 2105, last paragraph).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-9, 13, 14, 18, 20, 23, 25, 28, 29, 33, 60-63, and 80 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Anderson et al., US 6,200,347 B1. Regarding claim 1 and others, the slot of the pin (column 28, lines 59-62) defines a pair of spaced apart elongate portions each with a longitudinal axis; upon insertion of the pin, the outer surfaces of said (expanded) portions are inherently under tension, whereas the inner surfaces of said portions, along with the rest of the pin, are under compression. Regarding claim 2: column 28, lines 54-57. Regarding claim 7 and others: column 14, line 1 et seq.

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Claims 4-6, 10, 12, 19, 22, 26, 27, 72, 73, 86, 87, 114-116, and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., US 6,200,347 B1. Regarding claim 4 and others, the longitudinal axes of the pins and the pin sections being substantially along the fiber direction would have been immediately obvious, if not inherent, from the manufacturing procedure discussed at column 17, line 38 et seq., and illustrated in Figure 11B. Regarding claim 5 and others, the claimed fiber direction would have been obvious, if not inherent, from the methods depicted in Figures 11A and 12. Regarding claim 10, an L-shaped abutment would have been obvious in order to simplify the process of forming the interlocking means described at column 14, lines 2-20, especially when such a feature is to be supplemented with locking pins. Regarding claim 12 and others, the threaded pins (e.g., column 5, lines 43-50) likewise inherently possess portions under compression and portions under tension after insertion, and the through-holes being slightly offset from one another would have been obvious in view of the manufacturing tolerances associated with the holes and interlocking means and in view of the stresses to which the implant is subjected. Regarding claim 22 and others, Anderson et al. disclose various pin shapes, and to use a slotted pin in combination with a threaded pin, for example, would have been obvious in order to better stabilize the assembly against different types of stresses. Regarding claim 116 and others, the surfaces of the through-holes being demineralized would have been obvious, if not inherent, from column 12, lines 6-16. Regarding claim 127: column 19, lines 22-29; column 28, lines 13-14; column 29, line 21; etc.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Attention is directed to the drawings of US 6,139,211 and SU 590872.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Dave Willse
Primary Examiner
Art Unit 3738